Rifkin Broadens Challenge in Biotech

The battle waged by activist Jeremy Rifkin to bar the deliberate release of genetically engineered organisms into the environment continues. Rifkin is now fighting on several fronts to block plans by two biotechnology companies to conduct field tests involving genetically altered organisms and has, in effect, persuaded Stanford University researchers to delay field tests on modified corn plants. Rifkin has contended that the environmental consequences of such releases have not been adequately evaluated.

U.S. District Judge John Sirica in May barred a University of California experiment, approved by the National Institutes of Health (NIH) last year, that would have involved the first deliberate release of genetically modified organisms into the environment. Sirica told NIH not to approve any more field tests of modified organisms by university scientists, but his decision specifically exempted experiments performed by private companies. Rifkin has petitioned the court, NIH, and the Environmental Protection Agency (EPA) in order to close, or at least narrow, the loophole. (Meanwhile, the Justice Department has appealed Sirica's decision on the grounds that NIH is not required to produce a broad environmental impact statement before permitting field tests.)

Rifkin on 15 June requested that NIH director James B. Wyngaarden refrain from approving any experiments involving deliberate release until the agency develops a comprehensive plan to analyze the environmental impact of this type of experiment. Two weeks earlier, an NIH advisory committee recommended that two companies, which voluntarily submitted their proposals for review, be allowed to carry out experiments involving the release of genetically altered organisms. One of the companies plans to conduct an experiment that is virtually identical to the University of California field test that was approved by NIH and halted by Sirica's decision.

Wyngaarden said in an interview last week that he has not yet decided whether to accept the committee's recommendation to approve the experiments. A staff report has not been completed, and, according to one NIH official, a decision may not be made until September. Wyngaarden is faced with a difficult choice because approval of the experiment would create a double standard in which universities are barred from conducting experiments that companies can perform.

Like the University of California, Advanced Genetic Sciences plans to test strains of bacteria which have been genetically altered to prevent the formation of frost. The other company, Cetus Corporation, wants to field-test plants genetically modified to resist diseases. The companies presumably will wait for Wyngaarden's decision before proceeding, but they are not legally bound to do so.

Rifkin has also petitioned EPA to regulate the industry experiments. Rifkin argues that current EPA pesticide law gives the agency authority to regulate the bacterial tests planned by Advance Genetic Sciences. An agency permit, Rifkin asserts, must be obtained by the firm before it can test the bacteria in the open. The permit process, which requires a company to supply data on the ecological effects of its product, is usually triggered when an applicant wants to test a pesticide on 10 acres or more. The agency has not yet decided whether a permit is required to test the frost-preventing bacteria, according to officials.

EPA policy analyst Frederick Betz says that EPA pesticide regulations are not applicable to the plant experiments proposed by Cetus. However, the experiments might be subject to federal authority under a novel interpretation of toxic substances regulations at EPA or pesticide rules at the Agriculture Department. Rifkin's petition comes at a time when top agency officials are reviewing a draft policy that would define EPA's regulatory role concerning gene-splicing products.

Rifkin has also gone back to U.S. District Court seeking a preliminary injunction to halt the industry experiments. Specifically, Rifkin is seeking a court order that would force NIH to set aside approval of the experiments by the advisory committee until an environmental analysis is performed.

Whatever the outcome of this latest maneuvering to stop companies from field-testing, Rifkin's efforts have led to a postponement of the second of two university field tests that were approved by NIH and that scientists were ready to begin. In addition to the delay of the University of California experiment, Stanford scientists announced on 29 June that they would postpone an experiment involving the planting of corn seed containing recombinant DNA. The research would have tested a gene-splicing technique that, if successful, would have changed the color of corn kernels from white to purple.

Rifkin is now taking industry to task to stop field tests of organisms made by gene splicing.

Researchers Ronald W. Davis and Virginia Walbot came to the decision shortly after Rifkin's attorney, Edward Lee Rogers, notified Stanford on 21 June that his client had objections to the experiment, citing Sirica's ruling on the frost-preventing bacteria. Rifkin said in an interview that his complaints about the Stanford experiments were the same as those concerning the University of California, asserting that they were not adequately reviewed by NIH for environmental impact.

Rifkin's objections caught the Stanford researchers and lawyers by surprise. Walbot said they had been watching "with interest" the developments concerning the University of California, but believed they were unaffected "in any way" by the federal court's decision. Rodney Johnson, a Stanford lawyer, said that at the time Rogers called, the general counsel's office did not even have a copy of the federal court decision.

Walbot said she and Davis chose to delay the experiment to avoid the perception "of pulling a fast one." Stanford, which has been a leader in the discussion of genetic engineering, "has a special responsibility." Attorney Johnson says his office is now keeping in touch with the University of California and NIH. "If there are steps we can take to help, we'll consider them," Johnson said.

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